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AccuVein®

AV300 Operating Guide

A health professional's guide
for basic use and operation

AV300 Operating Guide

A practitioner's guide for basic use and operation

AV300 Operating Guide © AccuVein, LLC 2009

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Device fully complies with European Directive 2002/364/EC. Conformité Européenne.

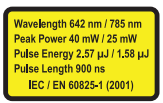
CE
0086

IEC/EN 60825-1 Safety of Laser Products:

Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

Shown at Right: Laser Classification Notice

Shown at Right: Laser Product Notice



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This manual last revised: June 26, 2009

Warnings and Cautions

Read all instructions, cautions, and warnings prior to use. This product should be operated only by qualified medical professionals. The AV300 should not be used as the sole vein location method, and it is not a substitute for sound medical judgment and the visual and tactile location of veins.

Before using the AV300 on a patient, qualified medical professionals must read and understand this AV300 Operating Guide and the AV300 User's Manual, which may be found on the DVD provided with the device. Qualified medical professionals contemplating use of the AV300 also should become familiar with how to properly position the device by following the instructions below. Before first use, users should compare how the AV300 detects veins with visual detection and palpation techniques. All vein location using the AV300 should be confirmed with appropriate medical judgment based on visual and tactile vein location and assessment techniques.

Patient and User Safety — Warnings

WARNING: The AV300 enables location of certain peripheral veins and is not a substitute for sound medical judgment based on the

visual and tactile location and assessment of veins. The AV300 should be used only as a supplement to the judgment of a qualified professional.

WARNING: The AV300 should only be operated when its battery is sufficiently charged (indicated when the battery icon at the upper right of the LCD screen has a bar inside battery outline), or when the device is operated in a powered hands-free stand to ensure AV300 is available for use.

WARNING: The AV300 displays only peripheral veins, and does so only to limited depths dependent on a variety of patient factors. The AV300 does not indicate vein depth.

WARNING: Do not shine vein display light in eyes.

WARNING: Do not hold the AV300 while performing venipuncture or other medical procedures.

WARNING: Keep the AV300 and its battery out of the reach of children.

WARNING: AV300 vein location is dependent on a variety of patient factors and may not display veins on patients with deep veins, skin conditions, hair, scarring or other highly contoured skin surface, and adipose (fatty) tissue.

WARNING: To view vein location accurately, you must position the AV300 at the proper height and angle, and directly over the center of the vein being assessed.

Patient and User Safety — Cautions

CAUTION: Blink reflexes can be inhibited or reduced by disease, drugs, or other medical conditions. For patients who might have inhibited or reduced blink reflexes, AccuVein recommends outfitting the patient with a protective eye shield. A protective eye shield capable of blocking 642 nm and 785 nm should be used. A commercially available, laser-safe eye shield that's suitable for eye protection is the "Glendale Laser-Aid Eye Shield." Glendale™ and Laser-Aid® are trademarks of their respective owners.

CAUTION: Operation or use of the AV300 in a manner different than specified in this AV300 Operating Guide and the AV300 User's Manual may result in hazardous radiation exposure.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or other qualified medical professional.

CAUTION: For external use only.

Equipment Care— Warnings

WARNING: Do not immerse the AV300, the AV300 charging cradle, or the AV300 hands-free stand in liquid or get the AV300 or its components so wet that liquid spills off.

WARNING: Do not attempt to sterilize the AV300 with heat or pressure sterilization methods.

WARNING: The AV300 will not display veins if operated outside its temperature range.

WARNING: Electromagnetic Interference (EMI) can affect the proper performance of the device. Normal operation can be restored by removing the source of the interference.

WARNING: Do not attempt to open, disassemble, or service the battery pack. Do not crush, puncture, short external contacts or dispose of in fire or water. Do not expose to temperature above 60°C / 140°F.

WARNING: To reduce the risk of fire or shock hazard and annoying interference, use only the recommended accessories and do not expose this equipment to rain or moisture.

WARNING: Use only AccuVein accessories and replacement parts with the AV300. The use of non AccuVein accessories may degrade safety.

WARNING: The USB port under the battery cover should never be used in a patient environment.

Equipment Care— Cautions

CAUTION: Use only AccuVein approved battery charging accessories, AccuVein BA300 batteries, and AccuVein brand powered stand. If the AV300 will not be used for an extended time, remove and store battery in a safe, dust-free location.

CAUTION: Dispose of used batteries according to manufacturer's instructions. A lithium ion battery that is recyclable powers the AV300. Please call AccuVein at (816) 997-9400 for information on how to dispose or recycle this battery.

CAUTION: Do not disassemble. The AV300 contains no customer serviceable components. The AV300 and its accessories should be serviced only by an authorized AccuVein repair department.

Should the vein display light need to be turned off immediately, press and hold the blue side button for at least ½ (one-half) second.

The AV300 battery should only be charged using an AccuVein battery charger, and replaced as instructed in this manual only with an approved AccuVein battery. If the AV300 is not going to be used for an extended period of time, the battery should be removed for

storage. Removing or replacing the battery (BA300) is not to be done in the patient environment.

A qualified medical professional may locate certain peripheral veins and may observe the center of those veins using the AV300. Depending on the distance the AV300 is held from the skin, the displayed vein might be slightly wider or narrower than the actual vein. Also, if the AV300 is not held directly over the vein, the vein may be displayed offset from its true position. For accurate vein presentation, the AV300 should be held at the height, angle, and centered position described in this *AV300 Operating Guide* and the *AV300 User Manual* available on the *AV300 DVD*.

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1 About This Guide

This operating guide provides an overview of how to operate the AV300. Additional details including recommended techniques, instructions on using advanced features of the AV300, and optional accessories can be found in the AV300 User Manual on the DVD that accompanies the AV300. The AV300 User Manual can also be downloaded from www.accuvein.com/og.

NOTE: The photographs in this AV300 Operating Guide may show prototype products. The available device and accessories may incorporate changes. AccuVein reserves the right to discontinue or modify products and accessories.

2 Setup

The AV300 Vein Viewing System includes an AV300 vein viewer with rechargeable battery, a charging cradle and power supply, documents including a practice card, an instructional DVD, and other accessories. The first time the AV300 is turned on, the language needs to be selected – default is English. For more information on setting device language, see User Manual on the supplied DVD.

NOTE: AccuVein recommends fully charging the AV300 before first use.

NOTE: Remove the plastic protective cover from the LCD before use

WARNING: Inspect power cords and supplies for damage. If any damage is found do not use until replacement is obtained.

CAUTION: Use only the AccuVein® PS310 power supply with the CC300 cradle and the HF300 powered hands-free stand.

AccuVein also offers optional hands-free stands that many practitioners find useful, as well as carrying cases and mobile solutions for practitioners who travel. For information about these and other optional accessories, visit the AccuVein web site.

To ensure the battery remains charged and ready for use, store the AV300 in its charging cradle or the HF300 powered hands-free stand. Follow the instructions that came in the HF300 kit box when using the HF300.

The CC300 charging cradle is not to be used in the patient environment.

3 Intended Use

The AccuVein® AV300 is a portable, hand-held instrument that helps qualified medical professionals to locate certain peripheral veins. The AV300 is intended to be used only by qualified medical personnel and as a supplement to appropriate medical training and experience. The AV300 should not be used as the sole vein location method, and it is not a substitute for sound medical judgment and the visual and tactile location and assessment of veins.

When used properly, the AV300 enables users to locate certain peripheral veins in connection with medical procedures, such as venipuncture.

The AV300 can be used whenever vein location is appropriate.

4 Product Description

The AV300 operates by using infrared light to detect veins beneath the skin, then illuminating the position of the veins on the skin surface directly above the veins. Qualified medical personnel can observe the vasculature as displayed to assist them in finding a vein of the right size and position for venipuncture.

The AV300 only shows peripheral veins. The maximum depth that veins are displayed varies by patient. In addition, some patients' veins or a portion of their veins might not be displayed well or at all. Causes for less than optimal or lack of vein display include, but are not limited to, vein depth, skin conditions (e.g., eczema, tattoos), hair, scarring or other highly contoured skin surface, and adipose (fatty) tissue.

When held directly overhead, the AV300 accurately locates the center of a vein. Increasing the displacement from directly overhead results in an offset in the displayed vein position.

WARNING: AV300 vein location is dependent on a variety of patient factors and may not display veins on patients with deep veins, skin conditions, hair, scarring or other highly contoured skin surface, and adipose (fatty) tissue.

The AV300 is not intended to be used as the sole method for locating veins, and should be used only by a qualified medical professional, who should do so either prior to palpation to help identify the location of a vein, or afterwards to confirm or refute the perceived location of a vein. When using the AV300, practitioners should always follow the appropriate medical protocols and practices as required by their medical facility, as well as exercising sound medical judgment.

The AV300 requires no routine or preventative maintenance.

The AV300 is portable internally powered by battery and approved for continuous operation. The AV300 is considered a Type B applied part and is not protected by ingress of water.

5 Contraindications

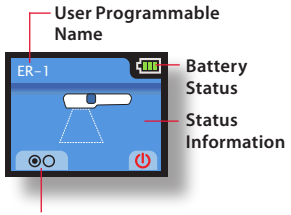
The AV300 should not be used to locate veins in or near eyes.

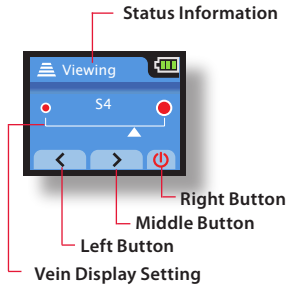
The AV300 is not intended to be used as a diagnostic device or for treatment of any kind.

6 User Controls and Screens

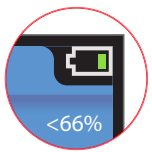
Note:
To turn OFF the vein display light at any time, press the right on/off button if active or press and hold the blue side button.

AV300 Controls at a glance	
Power AV300 ON	Press the blue side button or the Power button beneath the LCD screen on the right
Turn vein display light ON or OFF	While the AV300 is powered ON, press the blue side button for ½ (one-half) second
Cycle through vein display settings	While the vein display light is ON, lightly tap the blue side button
Power AV300 OFF	Press the blue side button for 2 seconds, or press the Power button beneath the LCD screen on the right





7 Operating the AV300

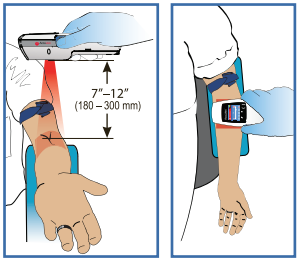


AccuVein recommends that the AV300 only be operated when its battery is charged to 16% or greater of full charge (indicated by a bar within the battery icon), or when the device is operated in a powered hands-free stand. Greater than 35% charge level is indicated when the battery icon at the upper right of the LCD screen shows a green bar.

Positioning the AV300

WARNING: The AV300 enables location of certain peripheral veins and is not a substitute for sound medical judgment based on the visual and tactile location and assessment of veins. The AV300 should be used only as a supplement to the judgment of a qualified professional.

WARNING: To view vein location accurately, you must position the AV300 at the proper height and angle, and directly over the center of the vein being assessed. The User Manual has additional detail on proper positioning of the AV300.

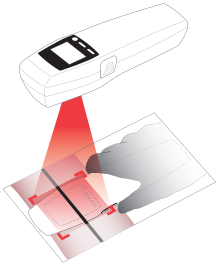


Hold the device approximately 7 inches (180 mm) over the surface of the skin and at a right angle (perpendicular) to the direction of the veins. Also make sure the vein display light is centered directly above the vein's center line. Don't move or rotate the device to either side of the vein or this will offset the projected vein from its true location beneath the skin. You can then often enhance display quality by adjusting the height and angle slightly. In particular, moving the device closer or further from the skin can help bring additional veins into view, depending on the patient's vasculature, room lighting, and depth of the veins. The User Manual has additional detail on proper positioning of the AV300.

Using the Practice Card

To test the AV300 before using it on a patient, use the practice card provided with the device.

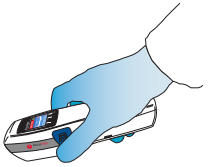
Place the white side of the card face up. Turn on the AV300 and its vein display light by pressing the blue side button. Hold the AV300 centered over the square about 7 inches (180 mm) from the bottom of the AV300 to the surface of the card, so the vein display light fits



within the red corner marks. Adjust the height of the AV300 so the light fills the square. When you hold the device properly, a "vein" should appear on the practice card that connects with the vein drawn on either sides of the display field. Try rotating the AV300 and you'll notice that the simulated vein starts to disappear as you get further out of line with it. Return the device to an approximate right angle with the vein to return the vein to view. You can try the AV300 on the back of your hand or on your arm to get a feel for how this works.

Basic Steps to Remember

Press the blue side button

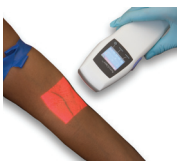


Press the blue side button to power on the AV300 and turn on the vein display light. While the light is on, quickly tap the blue side button to cycle through various vein display settings and select the one that works best for your patient and procedure. To turn the vein display light off, press the blue side button for ½ (one-half) second. This leaves the device on so you can use the LCD screen. Press the blue side button again to turn the vein display light back on and begin locating veins again. To power off both the light and the AV300, press the blue side button for two seconds.

WARNING: Do not shine vein display light in eyes.

CAUTION: Blink reflexes can be inhibited or reduced by disease, drugs, or other medical conditions. For patients who might have inhibited or reduced blink reflexes, AccuVein recommends outfitting the patient with a protective eye shield. A protective eye shield capable of blocking 642 nm and 785 nm should be used. A commercially available, laser-safe eye shield that's suitable for eye protection is the " Laser- Aid Eye Shield." Glendale™ and Laser-Aid® are trademarks of their respective owners.

Assess The Vasculature



While the vein display light is on, shine the AV300 over the patient's skin. You can do this before palpation, scanning quickly over the skin to help narrow down possible locations, or after palpation has confirmed vein location and suitability.

Be sure to position the AV300 at the proper height, angle, and centering as described above. You can then often see veins better by rotating the AV300 slightly on its axis, moving the device closer to or further away from the skin, and lightly tapping the blue side button to cycle through vein display settings. You can also select a setting using the LCD display.

Confirm The Vein

After assessing the patient's vasculature, confirm the site for your procedure by verifying the location and suitability of the vein using normal medical techniques and good medical judgment, such as vein visualization, palpation, and other medical techniques.

If performing venipuncture

If you're performing venipuncture, hand the AV300 to an assistant to hold so both of your hands remain free to perform the procedure. You can also use the AV300 in an optional hands-free stand, available at the AccuVein Web site. The AV300 should be used only by qualified medical professionals and only in conjunction with appropriate visual and tactile vein assessment techniques.

8 Charging the AV300

When the AV300 battery gets low (the battery indicator flashes yellow or red), you should charge the battery by placing the device in its charging cradle with the LCD screen facing outward. While the AV300 is in its charging cradle, the vein display light does not operate and the device cannot be used. When the AV300 is charging, the animated battery charge icon will display.

If the device is being used where there is no reliable source of electricity, additional batteries can be charged using the optional standalone battery charger and used as replacements, as necessary.

In normal operation, the AV300 battery needs to be replaced about every two years. Longer charge cycles, shorter operating periods, and the bad battery alert are all indications that the battery should be replaced.

To replace the battery, open the battery compartment on the narrow end of the device's underside. Use a screwdriver or edge of a small coin. Be careful not to touch or scratch the lenses on the back

of the device. You can check a battery's charge while it's not in the device by inserting a pen or paper clip into the small hole in the battery. An indicator light will illuminate if the battery is sufficiently charged for at least 30 minutes of normal operation.

9 Cleaning and Disinfecting

WARNING: Users should inspect the AV300 and clean and disinfect the AV300 as required by their institution's policies to ensure that it is sufficiently clean before each use.

WARNING: Do not use AV300 if the vein display light window is scratched or dirty. The AV300 should be returned to AccuVein for servicing if the vein light window is scratched.

To clean the body of the AV300 and its charging cradle, use a cloth moistened with soap and water, 70% isopropyl alcohol, a 10% dilution of chlorine bleach in distilled water, or chlorhexidine. You can also use normal household disinfectants and wipes.

Do not immerse the AV300, the AV300 charging cradle, or the AV300 hands-free stand in liquid or get the AV300 or its components so wet that liquid spills off.

Do not scratch the vein display light window; clean only as directed.

Do not attempt to sterilize the AV300 with heat or pressure sterilization methods.

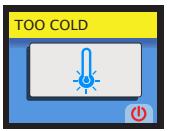
Do not clean the AV300 while in a charging cradle or hands-free stand.

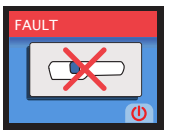
Do not clean the AV300 when the battery door is open or removed.

Unplug the charging cradle before cleaning the cradle.

For peak performance, the optical surfaces on the bottom of the AV300, and the lenses on the back of the device should be kept clean, as well. Use only a soft lens wipe with several drops of 70% isopropyl alcohol. Dirt or scratches on the vein display window show up as dark shadows in the vein projection.

10 Troubleshooting





If the AV300 detects that it cannot operate properly, it turns off the vein display light and displays an alert or fault screen. Alerts appear if you operate the device in an environment that's too cold (less than 5°C/41°F) or too hot (more than 40°C/104°F). Should a temperature alert occur, simply bring the AV300 back within its operating temperature range.

Other alerts indicate when the battery needs to be charged or replaced.

If the Fault screen appears, you should stop using the AV300 immediately. Turn off the device by pressing the right circular Power button under the LCD screen. Otherwise, the device will automatically turn off in 30 seconds. Then contact AccuVein support via telephone at (816) 997-9400.

11 Warranty Summary

AccuVein warrants the AV300, when purchased new from an authorized seller, is of sound materials and workmanship and conforms to the manufacturer's specifications for a period of one year from the date of purchase from AccuVein or its authorized distributors or agents. The warranty period for accessories is as follows: Charging Cradle – 1 year; Power Supply – 1 year; Battery – 90 days. AccuVein will repair or replace any product that does not satisfy these warranties within this time limit at no cost to the customer. You must obtain an RMA number from AccuVein technical support. Contact AccuVein support at (816) 997-9400 for service or additional information.

These warranties do not cover any misuse or abuse. These warranties are also void if the instrument is repaired by other than AccuVein or an authorized agent. There are no other warranties, either express or implied, other than those set forth in AccuVein's written warranty.

AccuVein has an optional Premium warranty service agreement that extends warranty coverage of the AV300 to 3 years.

This is only a summary of the AccuVein warranty coverage. Contact AccuVein, see the AV300 User Manual, or see www.accuvein.com/legal/warranty for full details of warranty coverage.

12 Limitation of Liability

In no event shall either AccuVein or the customer be liable to the other for any incidental, indirect, special or consequential damages (including without limitation lost profits or lost business opportunity) that the other party may incur by reason of its having entered into or relied on a purchase or lease agreement, or arising out of the performance or breach of such an agreement, even if the party against whom a claim is made was advised or knew of the possibility of such damages. The foregoing limitation shall apply regardless of the form of the claim in which such liability may be asserted, including breach of contract, tort (including negligence) or otherwise.

13 Specifications

General

Weight		275 grams (9.7 oz.)
Size		5 x 6 x 20 cm (2" x 2.4" x 7.9")
Battery		AccuVein® BA300 user replaceable Li-Ion 3.7V, 2,400 mAh
Continuous (vein light on) run time on full charge:		Typically 2 hours
Number of standard viewing procedures that can be performed using a fully charged battery		360
Charge time (full)		Typically 2 hours
Operating	Temperature	4°C to 40°C (39°F to 104°F)
	Humidity	5% to 85% RH non-condensing
Transport	Temperature	-20°C to 50°C (-4°F to 122°F)
	Humidity	5% to 85% RH non-condensing
Storage	Temperature	-20°C to 50°C (-4°F to 122°F)
	Humidity	5% to 85% RH non-condensing

Standards

IEC 60601-1 Medical Electrical Equipment Safety

IEC 60601-1-2 Electromagnetic Immunity

IEC/EN 60825-1 Safety of Laser Products

Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

UL 60601-1 Medical Electrical Equipment Safety

CAN/CSA C22.2 No. 601.1-M90 Medical Electrical Equipment Safety

Product Labels

Product and Serial Number Label

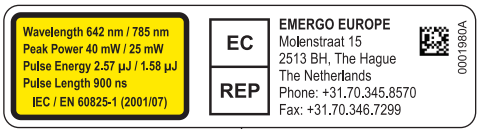
Location: Bottom of battery compartment

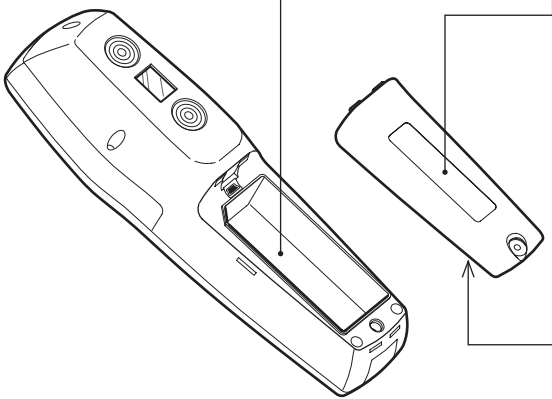
Laser Safety Label with Laser Classification Notice

Location: Outer face of battery compartment door

Information Label with Laser Product Notice

Location: Inner face of battery compartment door





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